Prioritization of Existing Substances under the Canadian Environmental Protection Act

OEHHA-COEH Workshop on Practical Decision-Making Tools for Identifying Safer Alternatives

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Overview

- Background
  - *The Canadian Environmental Protection Act*
  - Existing Substances
  - The Domestic Substances List
- Categorization – A Priority Setting Exercise
  - Ecological
  - Human Health
- Canada's Chemicals Management Plan
  - The Challenge
- Screening Assessments

The *Canadian Environmental Protection Act*

- Covers a range of activities that can affect human health and the environment, and acts to address any pollution issues not covered by other federal laws.
- Managing chemical substances is a fundamental part of CEPA; shared by Ministers of Environment & Health
- Provides the regulatory framework and process for risk assessment and risk management of chemicals

Addressing Existing Substances under CEPA

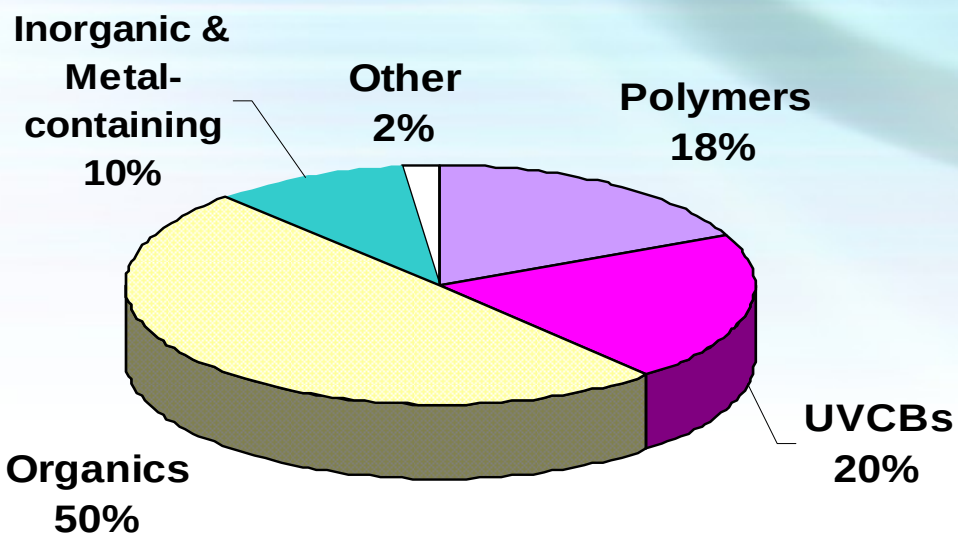
- CEPA 1988 (previous version)
  - Focused on pollution management
  - Priority Substance List assessments
    - In-depth, complex; 5 year legislated deadlines
    - PSL1 (n=44 substances, released in 1989)
    - PSL2 (n=25 substances, released in 1995)

- CEPA 1999 (revised in 1999)
  - Focus is on pollution prevention
  - Ministers' mandate expanded
  - Introduced Categorization of entire DSL (n = 23,000)
  - Screening assessments
  - Priority Substances List assessments

What is the Domestic Substances List (DSL)?

- A list of substances that are "in commerce" in Canada – "existing substances"
- It was created in 1991 with a list of substances which were between 1984-1986:
  - In Canadian commerce or used for commercial manufacturing in Canada, or;
  - Manufactured or imported in Canada at >100 kg/year
- DSL does not include: contaminants, by-products and wastes
- If a substance is not on the DSL, it is a "new substance", thus subject to data submission and review prior to introduction to Canadian commerce

Types of Substances on the DSL

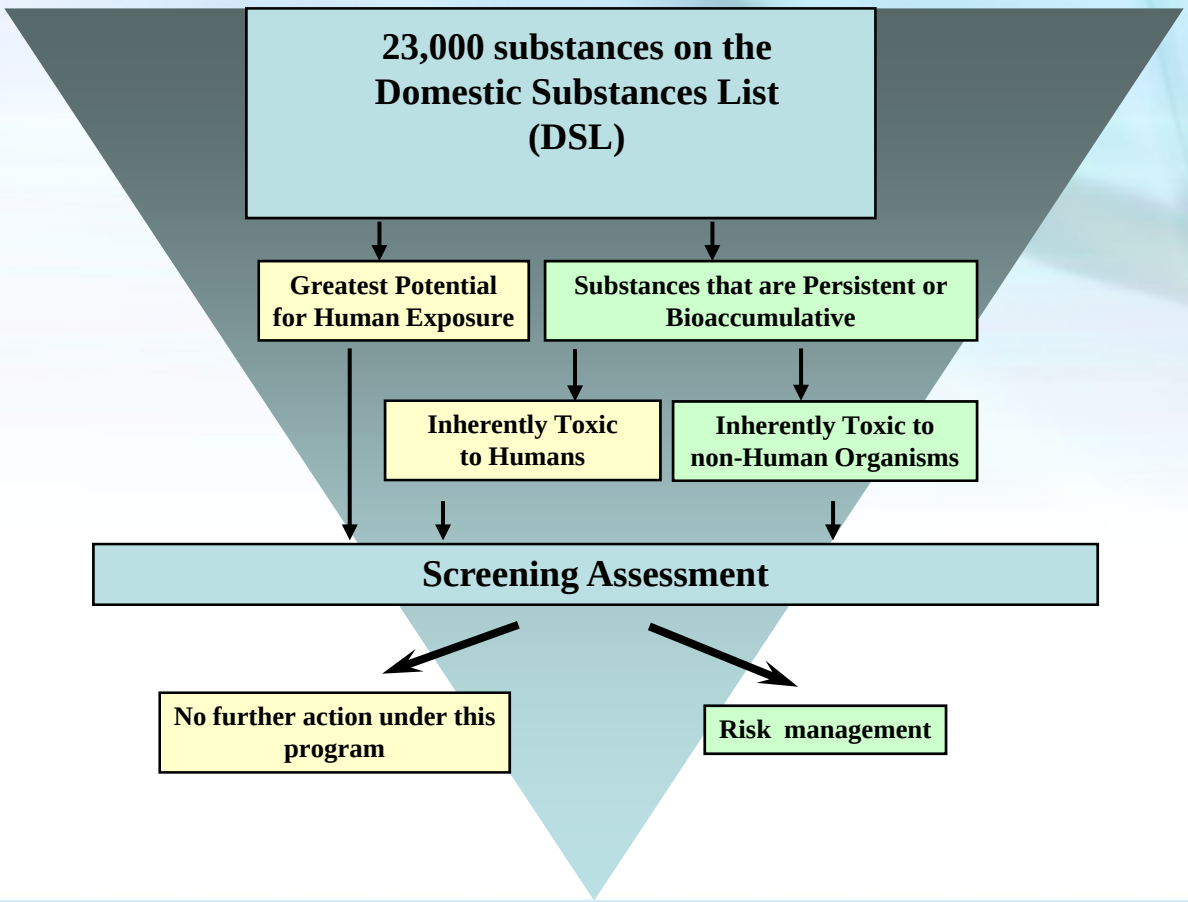


What was CEPA Categorization?

- CEPA 1999 required Ministers of the Environment and Health to categorize the 23,000 substances on the DSL according to specific criteria to identify substances that
    - May present, to individuals in Canada, the **greatest potential for exposure; or**
    - Are **persistent** (P) **or bioaccumulative** (B), in accordance with the regulations, **and inherently toxic** to humans or to non-human organisms, as determined by laboratory or other studies

- Categorization represented a priority setting exercise that involved the systematic identification of substances that should be subject to screening assessments and by extension management controls if applicable

The Categorization Process



What were the Categorization Challenges?

- No precedent, leading development of methodology
- Legislated deadline (7 years)
- Large number of substances had limited or no empirical data
- Varied types of substances on DSL
- Needed to develop an approach that was protective, transparent, scientifically credible

Ecological Categorization Criteria for P, B, and non-human iT

Bioaccumulation

BAF $\geq$ 5000
or
BCF $\geq$ 5000
or
log Kow $\geq$ 5

iT –non-humans

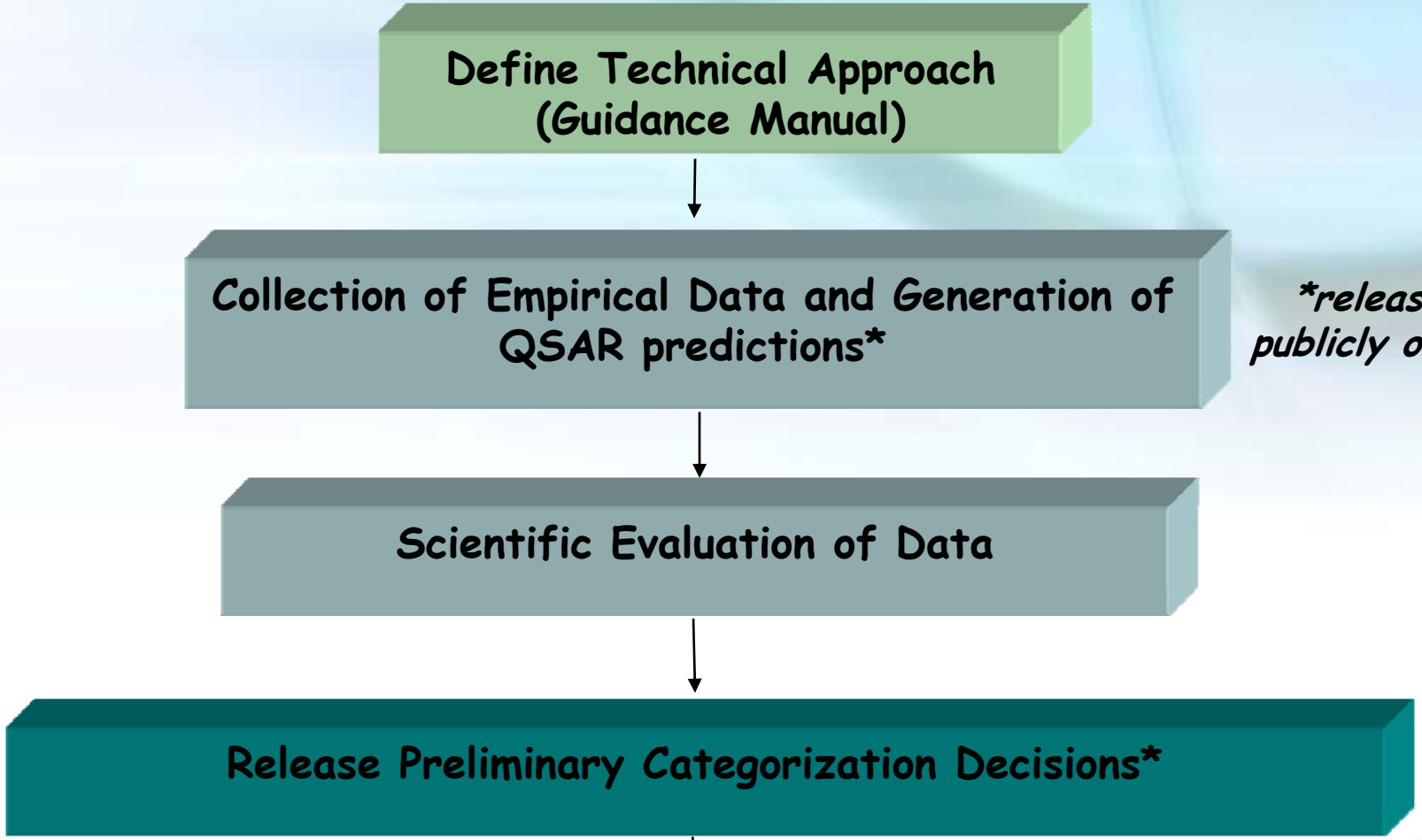
Acute aquatic toxicity of $LC(EC)_{50} \leq$ 1mg/L, or a chronic aquatic toxicity of NOEC $\leq$ 0.1 mg/L

Persistence

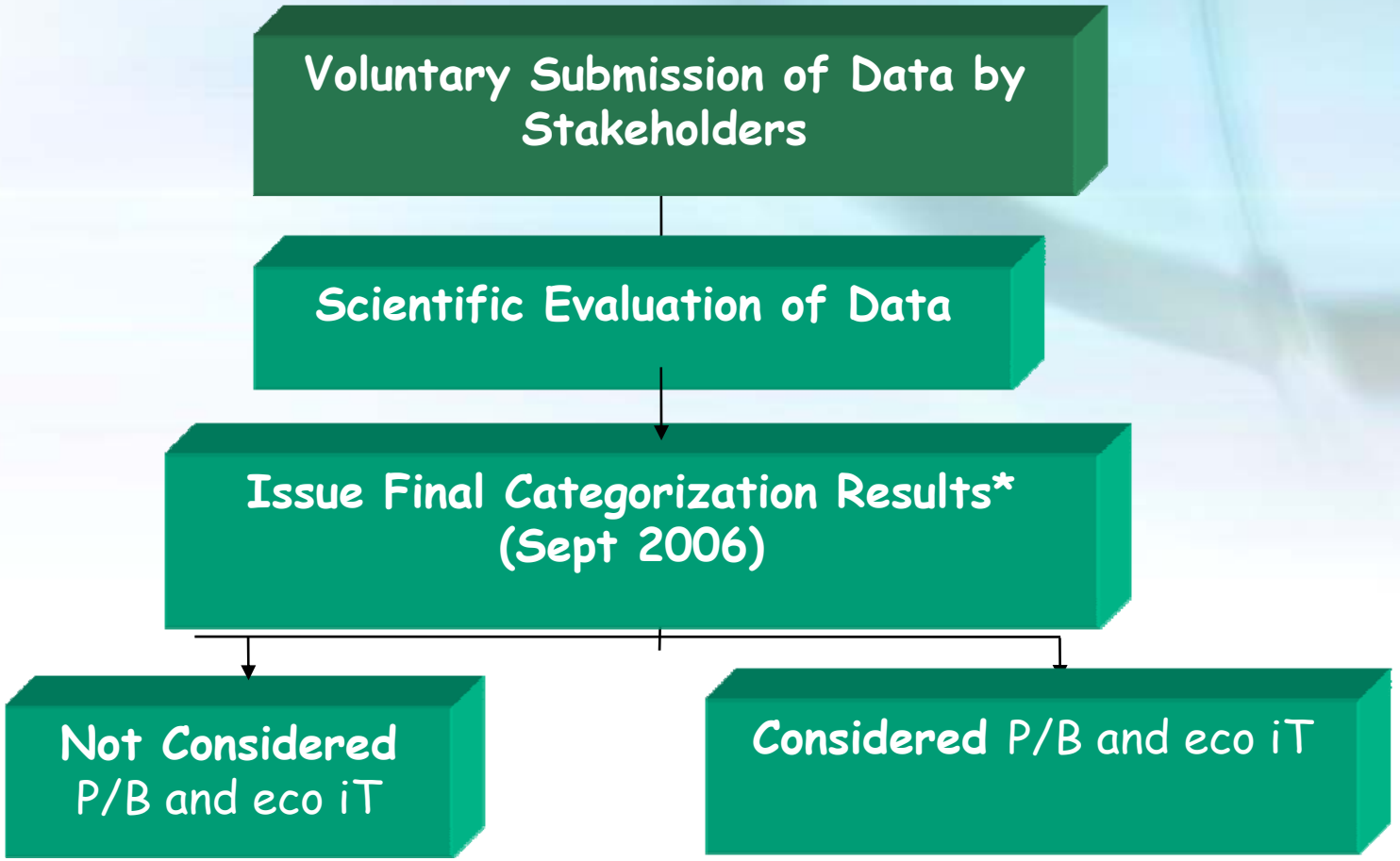
A substance is considered persistent if its transformation half-life satisfies the criterion in any one environmental medium or if it is subject to long-range transport

Medium	Half-life
Air	$\geq$ 2 days (or LRT)
Water	$\geq$ 6 months
Sediment	$\geq$ 1 year
Soil	$\geq$ 6 months

Process for Ecological Categorization



Process for Ecological Categorization (cont'd)



Key Areas of development for Technical Approaches and Strategic Guidance

- Organics
  - DSL Technical Advisory Working Group (1999-2001)
  - October 2002 Technical Workshop
  - Guidance Manual for the Ecological Categorization of Organic and Inorganic Substances on the DSL (2003)
- Inorganics
  - Inorganics Working Group (IWG) (2000-2001)
  - Findings and Recommendations from the IWG Report (2001)
  - Guidance Manual for the Ecological Categorization of Organic and Inorganic Substances on the DSL (2003)
- UVCBs
  - Golder Associates' Report on Developing an Approach for UVCBs (2003)
  - Boreal Associates' Report on Developing an Approach for UVCBs (2004)
  - Approach Document for Ecological Categorization of UVCBs (2005)
  - Category Approaches Documents (2005)
- Polymers
  - Approach Document for Ecological Categorization of Polymers (2005)
  - Category Approaches Documents (2005)
- Organometallics
  - Approach Document for Ecological Categorization of Organometallics (2005)

Information Sources

- Information Sources
  - Publicly available databases, journals, internet, international lists and data sources
  - Voluntary data submitted by Industry
  - Generated some phys-chem data and ecotoxicity data
  - Modelled data - QSARs (Quantitative Structure Activity Relationships)

Availability of Empirical Data

- Availability of Empirical Data
  - For more than 11,500 organic substances examined,
    - Experimental aquatic toxicity data was found for 1200 substances (80% accepted)
    - Experimental P data was found for 1500 substances (50% accepted)
    - Experimental B data was found for 440 substances (80% accepted)
  - 2100 substances on the DSL are also part of the US HPV program and 3140 are part of the OECD HPV program
  - The US HPV and OECD HPV programs provided:
    - Aquatic toxicity data for approx. 160 substances (70% accepted)
  - Persistence data for approx. 140 substances (90% accepted)
  - Bioaccumulation data for approx. 10 substances (90% accepted)

Data Preference for P B iT Profiles

Preference	P	B	iT
Higher	Experimental		
Medium	Analogue / Groupings / Scientific rationale		
Lower	Modelled (QSAR)		

Stakeholder Submission of Data

- June 2004, Canada launched an 18 month voluntary challenge to industrial stakeholders and interested parties to submit experimental study or other information that could help refine categorization decisions
- We received approx 20 larger data submissions for consideration and more than 400 individual studies addressing P, B or aquatic toxicity
- Approx. 20 submissions have been received covering the human health aspects of categorization

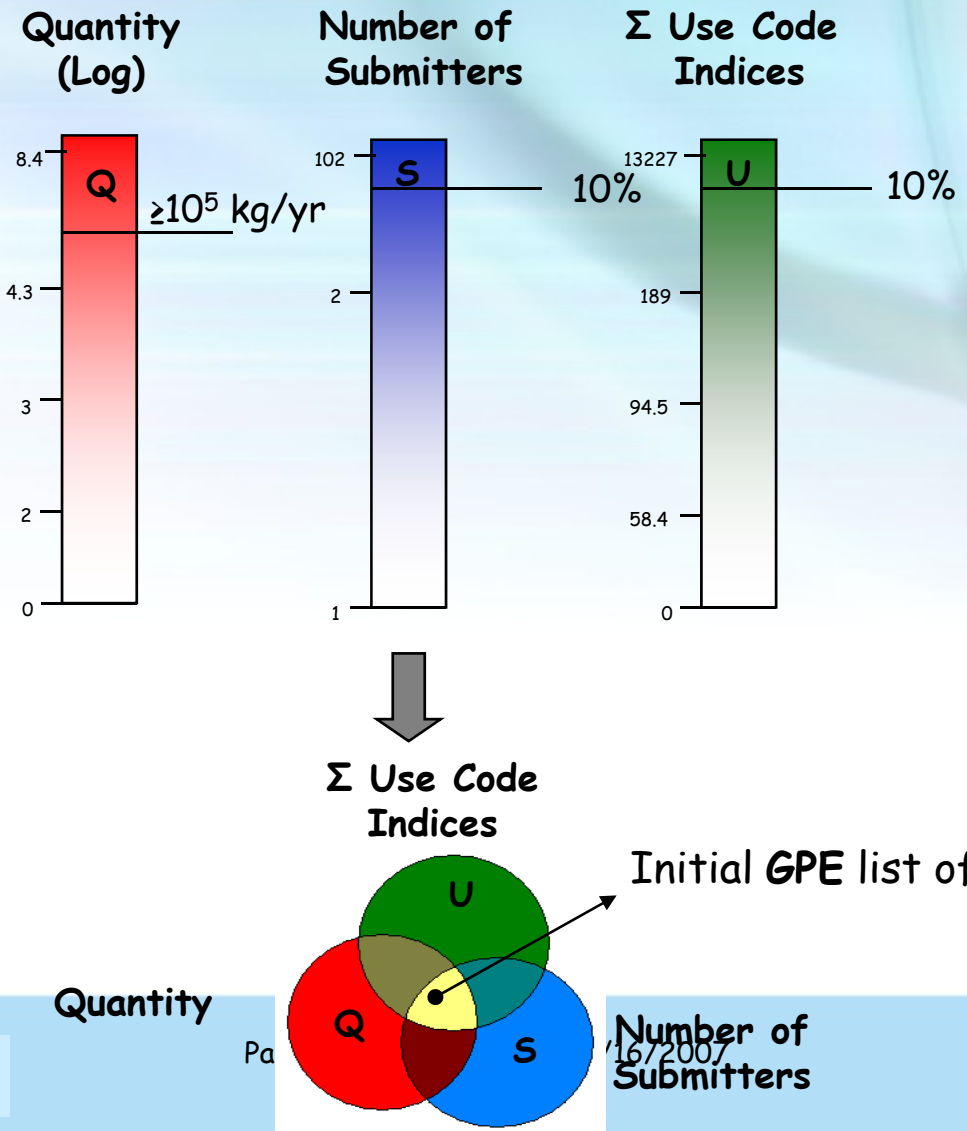
Categorization
Human Health Aspects

- Early recognition that legislative construct for categorization would not identify all priorities from human health perspective
- Persistence and Bioaccumulation not key determinants of potential to harm human health for all types of substances
- Other properties more relevant for some chemicals (e.g., reactive compounds)
- Simple and Complex Exposure and Hazard Tools developed to identify health priorities

The Simple Exposure Tool - SimET

- SimET is a relative ranking tool by which all substances on the Domestic Substances List have been "binned"
- Maximal use of the limited, comparable data for all 23,000 DSL compounds
  - Prevents bias to data-rich compounds
- Based on three different lines of evidence, derived from the limited information provided for all substances on the DSL:
  - quantity (estimated annual quantity of use, Q),
  - number of submitters (S)
  - use (sum of normalized expert ranked use codes, (U), reflecting two workshops
- Limited expert judgement

Simple Exposure Tool (SimET):
Relative Ranking for all DSL substances



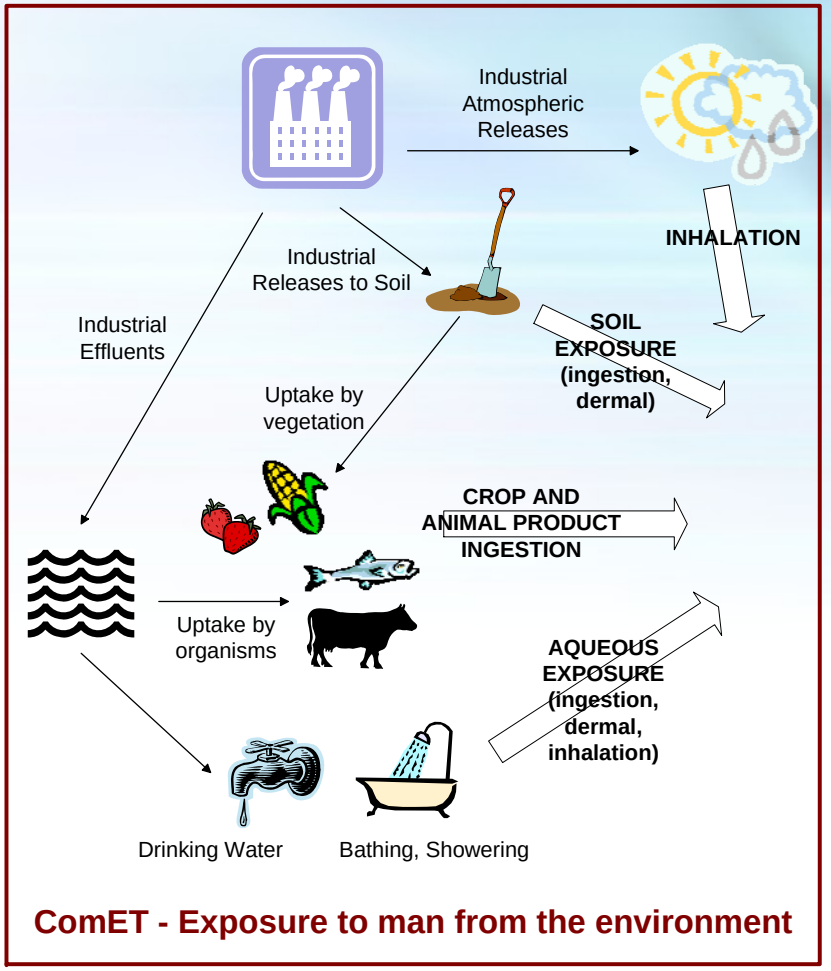
Criteria for Greatest, Intermediate & Lowest Potential for Exposure (GPE, IPE & LPE)

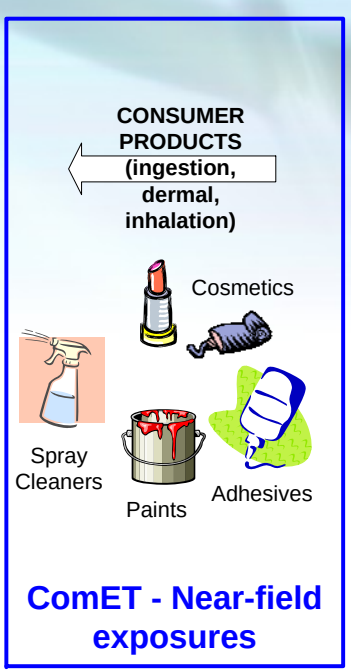
	Quantity (kg/year)	Number of Submitters	Sum of the Expert Ranked Use Code Indices
GPE	> 100 000	Top 10%	Top 10%
IPE	> 10 000	n.a.	Top 30%
LPE	All	All	All

ComET – the Complex Exposure Tool

- Provides plausible upper bound quantitative estimates of combined consumer (nearfield) & multimedia environmental (farfield) exposure by duration and age group, taking into account:
  - "Sentinel" product scenarios
    - Uses for a particular chemical likely to result in highest exposure
    - Based on upper bound of proportion used for generic function in a type of product
      - E.g., "solvent in paints", "polymers in adhesives"
  - Concentrations in environmental media of human exposure estimated based on extension of fugacity modelling

The Complex Exposure Tool (ComET)





The Simple Hazard Tool - SimHaz

- Applied to entire DSL
- Defines high or low hazard from classifications/assessments of other agencies based on weight of evidence
- Appropriate assessments selected based on comprehensiveness of review, peer review process, etc.

SimHaz Tool

- High Hazard Lists/Endpoints
  - Cancer (IARC, EU, HC, US EPA etc.)
  - Genotoxicity (EU)
  - Developmental Toxicity (EU)
  - Reproductive Toxicity (EU)
- Low Hazard Lists
  - PMRA 4a/US EPA 4a
  - OECD Low Concern

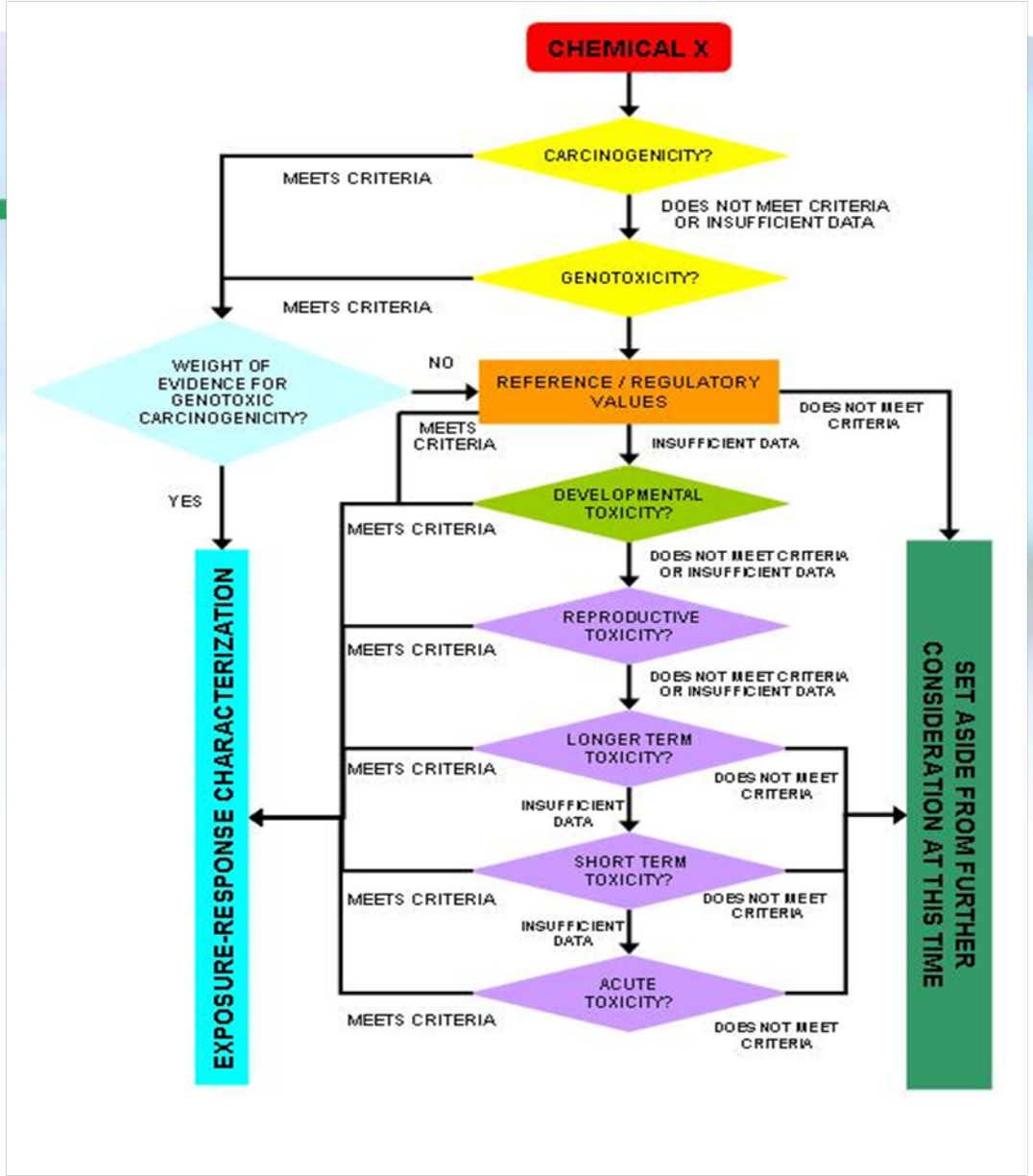
SimHaz Tool
Strengths and Limitations

- Strengths
  - Efficient
    - Takes advantage of critical review of others
  - Consistency
    - Assessments/classifications internationally
- Limitations
  - Bias towards data-rich substances

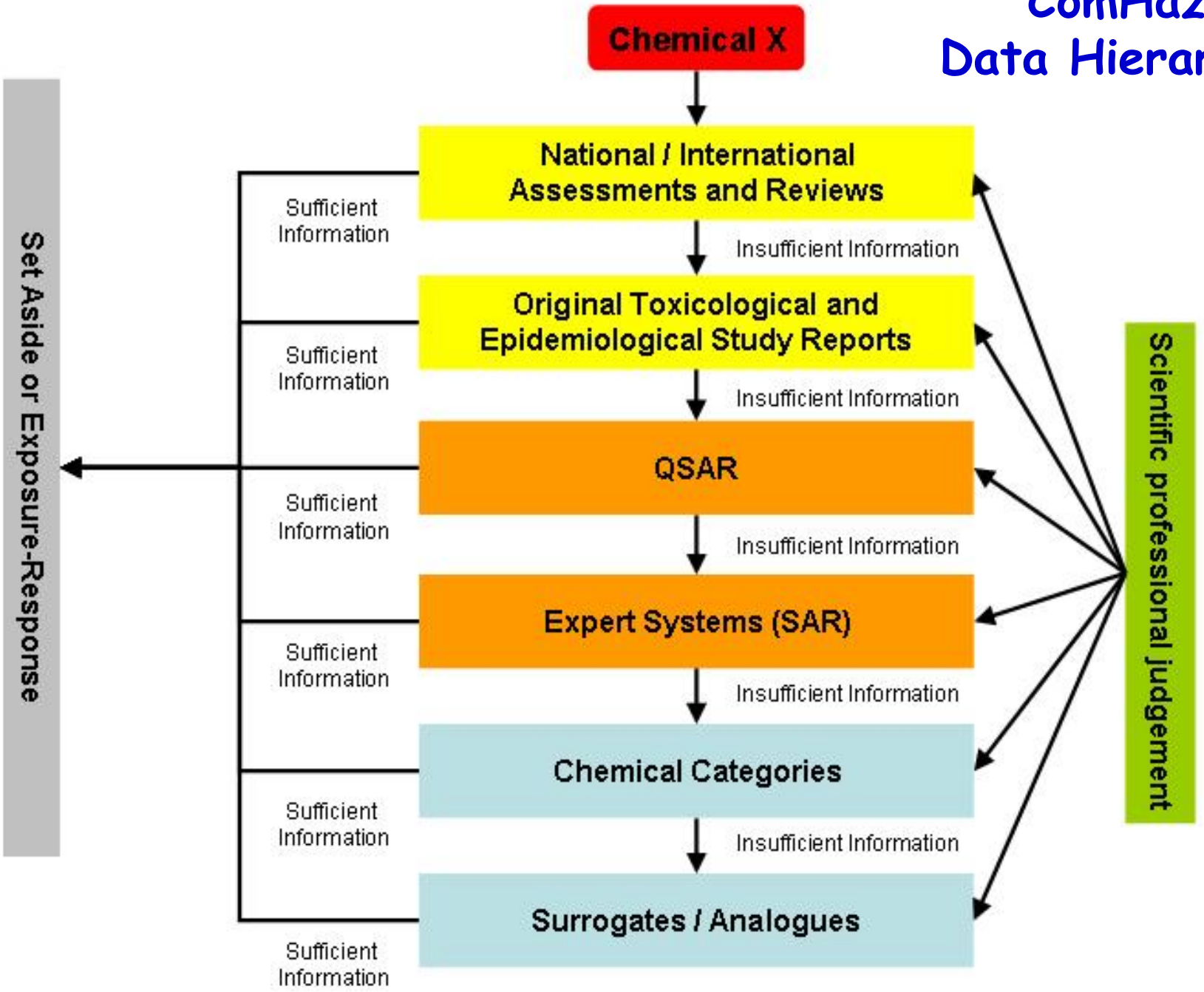
ComHaz Tool

- Hierarchical approach to consideration of
  - Multiple endpoints relevant to characterization of hazard
  - Sources of relevant information

ComHaz Hierarchy



ComHaz Data Hierarchy



ComHaz Tool – Endpoint-specific Criteria

Endpoint	Information Source	Criteria
Cancer	Data or (Q)SAR	1) Positive evidence 2) Weight of evidence
Genotoxicity	Data or (Q)SAR	1) Positive evidence 2) Weight of evidence
Regulatory/Reference Value	International & National Assessments	Ref Value ≤ 0.1 mg/kg bw/day
Developmental Toxicity	Data	NO(A)EL ≤ 90 mg/kg bw/day
	(Q)SAR	Positive Prediction
Reproductive Toxicity	Data	NO(A)EL ≤ 10 mg/kg bw/day
Longer Term Toxicity	Data or (Q)SAR	NO(A)EL ≤ 10 mg/kg bw/day
Short Term Toxicity	Data	NO(A)EL ≤ 30 mg/kg bw/day
Acute Toxicity	Data or (Q)SAR	LD_{50} ≤ 500 mg/kg bw

ComHaz Tool
Weight of Evidence (WoE)

Cancer/Genotoxicity

- First endpoints in the hierarchy and those for which capture rate is highest
- Confidence in (Q)SAR is greatest for these endpoints
  - Larger more diverse training sets (e.g., simple screening assays such as Ames test, specific sex/species combinations for cancer)
  - Potential for combining relevant endpoints
  - Relevance to specific modes of action
- Consistency with approach for PSL assessments that genotoxic carcinogenicity is critical endpoint

ComHaz Tool
WoE Cancer/Genotoxicity

- Incorporates separate lines of evidence, with differential weighting, including empirical data, QSAR/SAR results (CASETOX, TOPKAT, DEREK) & information from analogs
- Relative weighting of individual cancer & genotoxicity results, based on internal experience/expert consultation
  - For cancer, route of administration and numbers of species/sexes
  - For genotoxicity, predictive strength of various assays (i.e., in vivo vs. in vitro mutagenicity/clastogenicity assays > DNA damage > Indicator tests)

ComHaz Tool
Strengths and Limitations

- Strengths
  - Health protective
  - Comprehensive
  - High confidence in "set asides"
  - No bias towards data rich substances
  - Designed for high throughput
  - Takes advantage of critical reviews of others
  - Significant contribution of QSAR component to priority setting
  - External input, consultation, peer review
- Limitations
  - Resource intensive

Results of Categorization

- Categorization/Prioritization completed in September 2006
- Identified priorities for further work/action based on concern for:
  - Environment
  - Human Health
  - Environment & Human Health
- Of the 23,000 substances on the DSL, 4300 identified as priorities
  - 4000 met the categorization criteria
  - 300 warrant further attention from a human health perspective
- Set the stage for subsequent screening assessments

The Way Forward
The Chemicals Management Plan

- Following completion of categorization, Canada's Chemicals Management Plan (CMP) was introduced

- The CMP builds on categorization initiative to improve protection against hazardous substances

- Includes new, proactive measures to ensure chemical substances are managed properly

Key Objectives of the Chemicals Management Plan

- Significantly strengthen the existing substances regime:
  - Categorization established a new information baseline that sets clear priorities for action that are science based
- Integrate government activities:
  - Strengthen CEPA's coordination with other federal statutes, including: *Hazardous Products Act*, *Food & Drugs Act*, and *Pest Control Products Act*

Key Objectives of the Chemicals Management Plan (cont'd)

- Establish government accountability:
  - Enhanced monitoring and surveillance activities to identify priorities and measure effectiveness of regulatory actions
  - Increased research activities to ensure that action is informed by best available science
  - Enhanced risk communications to Canadians
  - Public web site to ensure consistent access to information
  - A cyclical update of the Domestic Substances List that will require industry to report on use and volume of substances on the Canadian market

- Strengthen industry's role in proactively identifying and safely managing risks associated with chemicals they produce and use

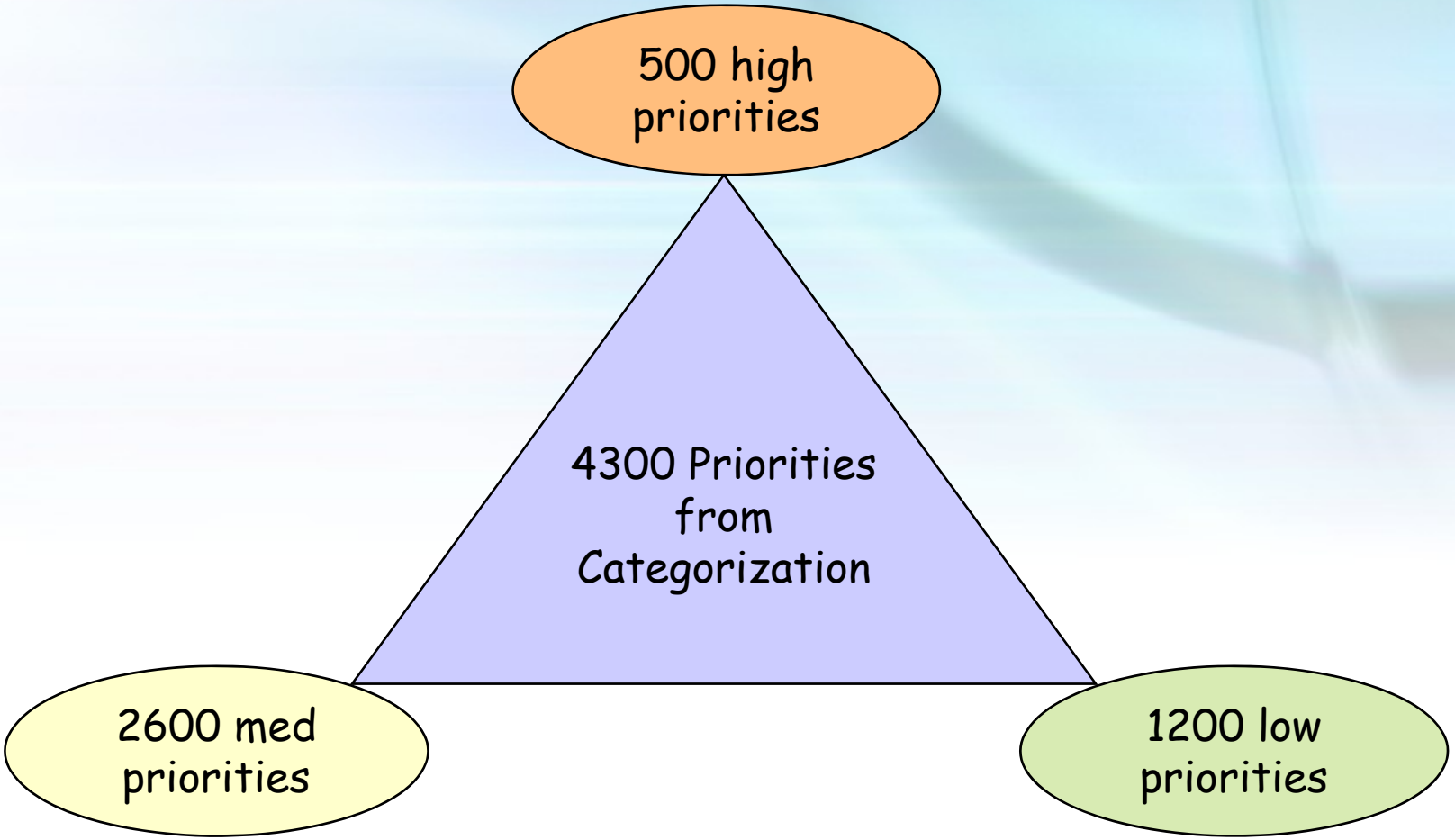
Furthering the Assessment of Existing Substances under the Chemicals Management Plan

- CMP directed that substances of highest concern of those identified in categorization be addressed
- Need to further prioritize substances identified during categorization exercise
- "Focus attention where attention is due"
- Capitalized on information gathered during categorization process

Prioritizing the Priorities

- Considerations for the following round of priority setting and upcoming actions :
  - The degree of hazard/risk
  - Commercial activity in Canada
  - Existing/ongoing risk assessment and risk management activities
  - Opportunities to engage internationally and "share the work" for a global issue

Prioritizing the Priorities



Low Hazard, Low Risk Substances

- A number of PiTeco or BiTeco substances identified through categorization have a low potential for risk
- Rapid screening employed for risk assessment used a worst-case scenario model to confirm the likelihood that a substance may not cause ecological harm
- Results were released for public comment on June 23, 2007
  - 1066 substances were subject to this approach
  - 754 substances were found to be "not toxic" to the environment according the definition in CEPA 1999
  - The government proposes to include the substances in the future inventory update to validate assumptions, conducting monitoring where appropriate and revisit some of the substances as part of assessments of "families of chemicals" at a later date
  - 312 substances require further assessment and re-prioritized into the group of medium priority substances

Medium priority substances

- The medium priority substances are expected to be addressed by 2020
- International programs, support for the research and monitoring community, and development and update of a cyclical inventory update will help the Government set priorities
- In addition, we will work with industrial sectors to negotiate and implement performance agreements

High Priority Substances

- High priorities for action included substances
  - That met each of the ecological categorization criteria (persistence (P), bioaccumulation (B) and inherent toxicity to aquatic organisms (iT), and believed to be in commerce in Canada and/or;
  - That met the criteria for greatest or intermediate potential for exposure (GPE or IPE) and were identified as posing a high hazard to human health (i.e., classified by another agency on the basis of carcinogenicity, mutagenicity, developmental toxicity or reproductive toxicity as identified by SimHaz Tool)

High Priorities

- Within the Chemicals Management Plan, the top priorities (identified through categorization) are addressed through 4 components:
  - Significant New Activity (SNAcs) for substances believed to not be in commerce
  - Petroleum Sector Stream – a focused sectoral approach
  - Substances that are already in the assessment or management stream
  - Challenge Program for substances believed to be in commerce (~ 200 substances)

Restrictions on Re-introductions and New Uses (SNAcs)

- Re-introduction of 148 high-hazard substances from categorization not currently in use in Canada controlled through the Significant New Activity (SNAc) provisions of the New Substances Program

- SNAc notice requires industry to provide data o be reviewed by Environment Canada and Health Canada before the substance can be re-introduced into Canada

Petroleum Sector Stream

- High priority petroleum substances were set aside from the Challenge because of the large number that are primarily or exclusively related to the petroleum sector
- Most are complex mixtures that may need to be considered differently from discrete substances
- Will be assessed within three years, with control measures, if appropriate, within CEPA timelines
- The Government is currently developing a work plan and will consult with stakeholders

The Challenge Program

- The Chemicals Management Plan relies on strong stewardship from the Canadian industry
- Challenge to stakeholders to provide data to:
  - Improve, where possible, PBiT data
  - Identify industrial best practices in order to set benchmarks for risk management and product stewardship
  - Collect environmental release, exposure, substance and/or product use information
  - Information about how it is managing these substances
- The absence of information will not preclude Government from taking action that safeguards human health and the environment

Why Canada is using a Challenge initiative to deal with the 200 priorities for action

The Ministers consider:

- Evidence that a substance is both Persistent and Bioaccumulative, when combined with evidence of toxicity and release into the environment, can lead to harmful ecological impacts. This indicates that the substance meets at least one of the criteria for "toxic" to the environment in CEPA 1999
- Evidence that a substance for which the critical health effect is assumed to have no threshold – i.e. a genotoxic carcinogen – it is assumed that there is a probability of harm to human health at any level of exposure, and therefore indicates that the substance meets the criteria for "toxic" to human health in CEPA 1999
- Evidence that a substance exhibits carcinogenicity, mutagenicity, developmental toxicity, or reproductive toxicity, and a high likelihood of exposure to individuals in Canada, indicates that the substance meets the criteria for "toxic" to human health in CEPA 1999

What is the "Challenge"?

- Publication, in batches of 15-30 substances every three months, a substance profile for industry and other stakeholders to comment on and provide any additional information in their possession (mandatory and non-mandatory responding)
- Stakeholders will have six months to comment on the profiles and provide requested information
- All challenge substances to be released within 3 years
- Government scientists will have a maximum of 6 months to review the information provided. The Government of Canada will then decide what actions are to be taken through an expedited application of CEPA (1999)
- Risk management actions for all substances will be implemented in accordance with the CEPA Process

Objectives of the Substance Profile Documents

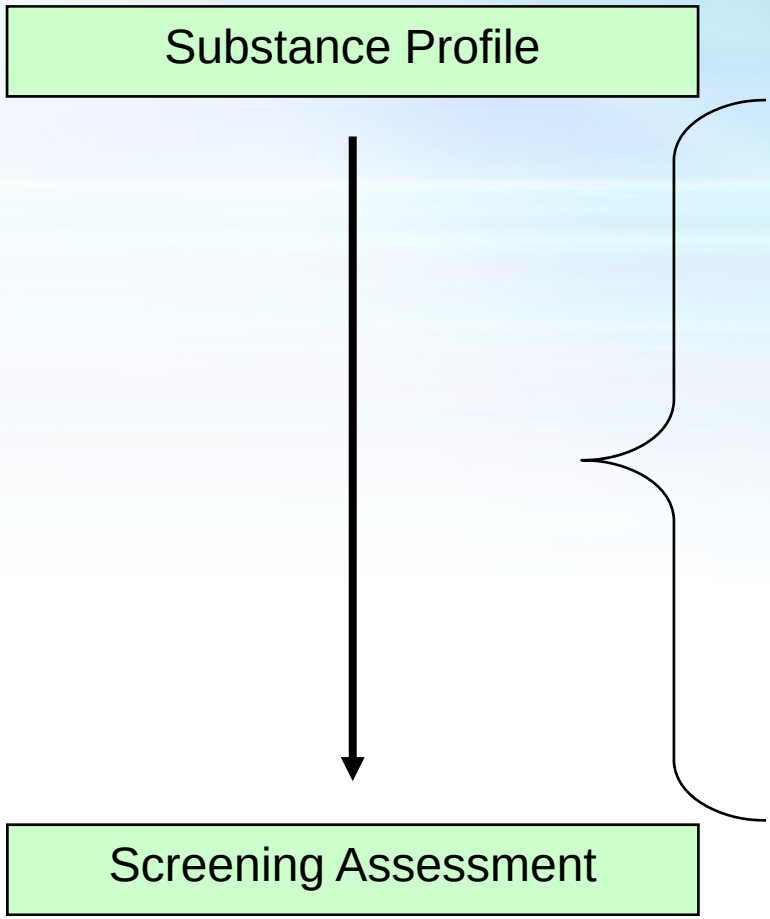
- Show stakeholders what we know about the substance.
- Justify, within the context of the Challenge, the basis for taking actions on a substance that was identified as a high concern through the categorization activities.
- Identify opportunities to submit information to support the activities taking place under the Chemicals Management Plan.

Screening Assessments

- For substances identified in the Challenge, screening level risk assessments are being prepared to address
  - Ecological aspects
  - Human health aspects
  - Ecological and Human health aspects

- Depending on the basis under which they were considered priorities for further work

Ecological Screening Assessments



As appropriate:

- Refine phys-chem properties
- Revise decisions on persistence, bioaccumulation and long-range transport
- Refine information on possible toxic effects, including information for non-aquatic organisms, where available
- Refine information on commercial activities and other potential sources of formation or release
- Refine summary of key uncertainties

Human Health Screening Assessments

- Generally, national/international classifications will be used as the basis for characterizing the hazard of these substances for the screening assessment
  - incorporates weight of evidence based decisions of these agencies
  - ensures consistency

- Consideration also of other health effects of potential concern beyond the basis for the classification based on evaluation of available information (including recently published peer-reviewed studies) in a screening context

- Characterization of population exposure and key sources

- Discussion of uncertainties

Prioritization & Assessment Past & Future

- Capitalize on past efforts to move forward on these substances through strengthened partnerships inside and outside the federal government to ensure the most efficient and effective protection of Canadians and their environment
  - Program expertise
  - Experienced stakeholder engagement relationships
  - Targeted legislative design

Contact Information

- Chemical Substances Website: http://www.chemicalsubstances.gc.ca

- CD-ROMS with results of DSL Categorization are available upon request.

Thank you!